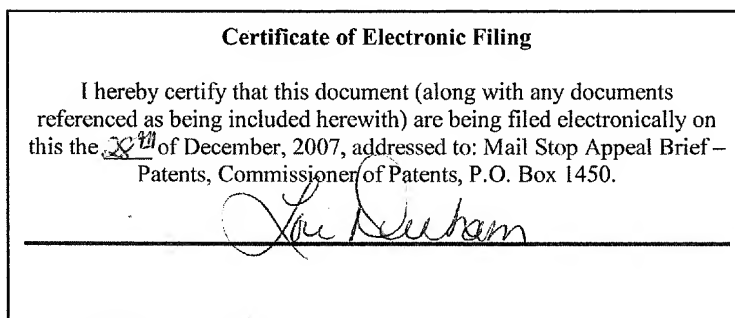


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | | | |
|-------------------|--|------------------|----------|
| Applicants: | Boyle, et al. | Attorney Docket: | 6006-107 |
| Serial No.: | 10/672,695 | Examiner: | C. Prone |
| Filed: | September 26, 2003 | Art Unit: | 3738 |
| Confirmation No.: | 9286 | Customer No.: | 29,335 |
| Title: | Implantable Graft and Methods of Making Same | | |



Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO EXAMINER'S ANSWER

Dear Sir:

This is responsive to the Examiner's Answer mailed on November 2, 2007 in the above-captioned patent application.

Applicants respond to two assertions made by the Examiner in Section (10) Response to Argument of the Examiner's Answer. The first assertion relates to lack of definition of the term "microporous", and the second assertion relates to definition of "passing through". Applicants direct attention to portions of the specification of the present application that refute these assertions.

1. Definition of “microporous:

While the Examiner states that Applicants fail “to provide a place in the specification wherein there is a definite definition of the term” microporous, Lines 24-28 of Paragraph No. [0010] of the specification provide a definition. Those Lines state:

The microporous metallic or pseudometallic thin film covering is also described in co-pending, commonly assigned U.S. Patent Applications S.N. 10/135,316 and 10/135,626, both filed on April 29, 2002, both of which are hereby expressly incorporated by reference as describing the microporous thin film covering.

Patent Application S.N. 10/135,316 issued as U.S. Patent No. 6,936,066, and Patent Application S.N. 10/135,626 published on October 25, 2007 as Pub. No.: 2007/0250156. To expedite review, copies of both of these documents are included. For the sake of clarity, Applicants direct attention to the following portions of the '066 patent which include definition of microporous as having microperforations: Column 1, lines 24-31 and 40-46, Column 5, lines 20-35, Column 6, lines 1-60, and Column 8, lines 15-38. Those sections are reproduced below.

Column 1, lines 24-31 - citing microperforations

More specifically, the present invention relates to implantable medical grafts fabricated of metallic or pseudometallic films of biocompatible materials having a **plurality of microperforations** passing through the film. The plurality of microperforations may serve multiple purposes, including, for example, permitting geometric deformation of the film, imparting a fabric-like quality to the film, and imparting flexibility to the film. (Emphasis supplied)

Column 1, lines 40-46 - microperforations pass through graft

As used herein the term "graft" is intended to indicate any type of device or part of a device that comprises essentially a material delimited by two surfaces where the distance between said surfaces is the thickness of the graft and that exhibits integral dimensional strength and that has **microperforations that pass through** the thickness of the graft. (Emphasis supplied)

Column 5, lines 20-35 - highlighting microperforations

In accordance with a preferred embodiment of the invention, there is provided a self-supporting graft member having a plurality of **microperforations** passing through the wall thickness of the graft. The graft member may assume virtually any geometric configuration, including sheets, tubes or rings. The plurality of microperforations may serve to impart geometric compliance to the graft,

geometric distendability to the graft and/or limit or permit the passage of body fluids or biological matter through the graft, such as facilitating transmural endothelialization while preventing fluid flow through the wall of the graft under normal physiological conditions. The plurality of **microperforations** may also impart a fabric-like quality to the graft by imparting pliability and/or elastic, plastic or superelastic compliance to the graft, such as that required for longitudinal flexibility in the case of a vascular graft. (Emphasis supplied)

Column 6, lines 1-60 - microperforation size and cellular migration

For some applications it is preferable that the size of each of the plurality of **microperforations be such as to permit cellular migration** through each opening, without permitting fluid flow there through. In this manner, for example, blood cannot flow through the plurality of microperforations (in their deformed or un-deformed state), but various cells or proteins may freely pass through the plurality of microperforations to promote graft healing in vivo. For other applications, moderate amounts of fluid flow through the plurality of deformed or un-deformed microperforations may be acceptable. For example, endoluminal saphenous vein grafts may be fabricated with microperforations that serve the dual function of **permitting transmural endothelialization** while also excluding biological debris, such as thrombus from passing through the wall thickness of the graft, effectively excluding detrimental matter from entering the circulation. In this example, each of the plurality of **microperforations in either their deformed or undeformed state, may exceed several hundred microns**.

Those skilled in the art will understand that a direct relationship exists between the size of pores and the overall ratio of expansion or deformability of an implantable graft. Generally, therefore, it is appreciated that pore sizes must increase in order to increase the effective attainable degree of expansion or deformation of the graft.

For applications where large deformation and small pore size are both requirements, in accordance with another aspect of the inventive graft embodiment, it is contemplated that two or more graft members are employed such as diametrically concentric grafts for tubular configurations. The two or more graft members have a pattern of a plurality of **microperforations** passing there through, with the plurality of patterned microperforations being positioned out of phase relative to one another such as to **create a tortuous cellular migration pathway through the wall** of the concentrically engaged first and second graft members as well as a smaller effective pore size. In order to facilitate cellular migration through and healing of the first and second graft members in vivo, it may be preferable to provide additional cellular migration pathways that communicate between the plurality of microperforations in the first and second graft members. These additional cellular migration pathways, if necessary, may be imparted as 1) a plurality of projections formed on either the luminal surface of the second graft or the abluminal surface of the first graft, or both, which serve as

spacers and act to maintain an annular opening between the first and second graft members that permits **cellular migration and cellular communication between the plurality of microperforations** in the first and second graft members, 2) a plurality of microgrooves, which may be random, radial, helical, or longitudinal relative to the longitudinal axis of the first and second graft members, the plurality of microgrooves being of a sufficient size to permit cellular migration and propagation along the groove, the microgrooves serve as cellular migration conduits between the plurality of microperforations in the first and second graft members, or 3) where the microperforations cause out of plane motion of the graft material upon deformation thereby keeping a well defined space between the planes originally defining the facing surfaces of the grafts. (Emphasis supplied)

Column 8, lines 15-38 - microperforation size

A plurality of microperforations 20 is provided and pass through the thickness 18 of the body member 12 with interperforation regions 22 of the body member 12 between adjacent microperforation 20. The plurality of microperforations 20 each preferably have a geometric configuration that is susceptible of geometric change, such that the open surface area of each microperforation 20 may change under an externally applied load. **Each of the plurality of microperforations 20 in the undeformed state preferably has an open surface area less than about 2 mm.sup.2, with the total open surface area of the graft in the undeformed state being between 0.001 to 99%.** The open surface area of the plurality of microperforations and the open surface area of the graft may change considerably upon deformation of the plurality of microperforations 20. Both the size of the microperforations 20 in the deformed and undeformed state and the total open area of the graft 12 in the deformed and undeformed state may be selected in view of the following non-exclusive factors based on the graft application: 1) the desired compliance of the graft 10, 2) the desired strength of the graft 10, 3) desired stiffness of the graft 10, 4) the desired degree of geometric enlargement of the microperforations 20 upon deformation and 5) in some cases, such as with vascular grafts, the desired delivery profile and post delivery profile. (Emphasis supplied)

Applicants respectfully submit that the preceding portions of the specification provide definition of microporous, and refute the Examiner's statement.

2. Definition of "passing through"

While the Examiner states that "the openings simply require that particles pass through them, which does not require the particles to pass out the other end of the opening", the referenced '066 patent specifically states that the openings or microperforations pass through the

thickness which is the distance between two surfaces. To facilitate review, Applicants provide relevant sections of the referenced '066 patent below.

Column 1, lines 40-46 - microperforations pass through thickness

As used herein the term "graft" is intended to indicate any type of device or part of a device that comprises essentially a material delimited by two surfaces where the distance between said surfaces is the thickness of the graft and that exhibits integral dimensional strength and that has **microperforations that pass through the thickness of the graft**. (Emphasis supplied)

Column 5, lines 20-35 - microperforations pass through thickness

In accordance with a preferred embodiment of the invention, there is provided a self-supporting graft member having a **plurality of microperforations passing through the wall thickness of the graft**. The graft member may assume virtually any geometric configuration, including sheets, tubes or rings. The plurality of microperforations may serve to impart geometric compliance to the graft, geometric distendability to the graft and/or limit or permit the passage of body fluids or biological matter through the graft, such as facilitating transmural endothelialization while preventing fluid flow through the wall of the graft under normal physiological conditions. The plurality of microperforations may also impart a fabric-like quality to the graft by imparting pliability and/or elastic, plastic or superelastic compliance to the graft, such as that required for longitudinal flexibility in the case of a vascular graft. (Emphasis supplied)

Column 6, lines 26-60 - microperforations pass through


For applications where large deformation and small pore size are both requirements, in accordance with another aspect of the inventive graft embodiment, it is contemplated that two or more graft members are employed such as diametrically concentric grafts for tubular configurations. The two or more graft members have a pattern of a plurality of **microperforations passing there through**, with the plurality of patterned microperforations being positioned out of phase relative to one another such as to create a tortuous cellular migration pathway through the wall of the concentrically engaged first and second graft members as well as a smaller effective pore size. In order to facilitate cellular migration through and healing of the first and second graft members in vivo, it may be preferable to provide additional cellular migration pathways that communicate between the plurality of microperforations in the first and second graft members. These additional cellular migration pathways, if necessary, may be imparted as 1) a plurality of projections formed on either the luminal surface of the second graft or the abluminal surface of the first graft, or both, which serve as spacers and act to maintain an annular opening between the first and second graft members that permits cellular migration and cellular communication between the

plurality of microperforations in the first and second graft members, 2) a plurality of microgrooves, which may be random, radial, helical, or longitudinal relative to the longitudinal axis of the first and second graft members, the plurality of microgrooves being of a sufficient size to permit cellular migration and propagation along the groove, the microgrooves serve as cellular migration conduits between the plurality of microperforations in the first and second graft members, or 3) where the microperforations cause out of plane motion of the graft material upon deformation thereby keeping a well defined space between the planes originally defining the facing surfaces of the grafts. (Emphasis supplied)

Applicants respectfully submit that these portions clearly indicate that the openings (microperforations) pass from one surface, through the thickness, to the other surface. This arrangement provides cellular migration pathways. Applicants respectfully submit that the Examiner's assertion has been refuted.

Applicants respectfully submit that the two assertions made by the Examiner in Section (10) Response to Argument of the Examiner's Answer have been disproven. As none of the cited references anticipate, suggest or render obvious all of the elements of Applicants' claims, all of the pending claims are allowable. Favorable action is solicited.

Respectfully submitted,



Mark C. Bach
Reg. No. 34,766

December 27, 2007

ROSENBAUM & ASSOCIATES, P.C.
650 Dundee Road
Suite #380
Northbrook, Illinois 60062
Direct Tel. (847) 770-6016
Fax. (847) 770-6006